ThermoFisher
SCIENTIFIC

510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K070824

A. Introduction:

DEC 0 3 2007

According to the requirements of 21 CFR 807.92 the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter's information

Name:	Thermo Fisher Scientific Oy
Address:	Ratastie 2 P.O. Box 100 FIN-01621 Vantaa Finland
Phone:	+358 (9) 329 100 tel
Fax:	+358 (9) 3291 0500 fax
Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	October 16th, 2007

C. Device name

Proprietary name:	CREATININE (Enzymatic), code 981845
Common name:	CREATININE (Enzymatic)
Classification:	Clinical Chemistry
Class:	II
Product Code:	JFY
Proprietary name:	sCal, code 981831
Common Name:	Calibrator, Multi-Analyte Mixture
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIX
Proprietary name:	Nortrol, code 981043
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY
Proprietary name:	Abtrol, code 981044
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

D. Intended Use

CREATININE (Enzymatic),
For *in vitro* diagnostic use in the quantitative determination of creatinine concentration in human serum, plasma or urine on T60 instrument using enzymatic method

sCal
For in vitro diagnostic use on T60 analyzer. sCal is used as a multicalibrator for quantitative measurements using methods defined by Thermo Fisher Scientific Oy.

Nortrol
For in vitro diagnostic use for quantitative testing on T60 analyzer. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Analyzers using methods defined by Thermo Fisher Scientific Oy.

Abtrol
For in vitro diagnostic use for quantitative testing on T60 analyzer. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Analyzers using methods defined by Thermo Fisher Scientific Oy.

E. Indications for use

The CREATININE (Enzymatic) is intended for quantitative in-vitro diagnostic determination of creatinine concentration in human serum, plasma (Li-heparin) or urine using T60 Clinical Chemistry Analyzers.
Measurement of creatinine levels aids in the diagnosis and treatment of certain renal disease,in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

For sCal Calibrator, Nortrol and Abtrol Controls see intended use

F. Substantial Equivalence

Roche Diagnostics Corporation, model COBAS Integra 700
Roche Diagnostics Corporation item:
COBAS Integra Creatinine plus ver.2 (K024098).

G. Substantial equivalence -similarities

CREATININE (Enzymatic) is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Roche Diagnostics Corporation COBAS Integra Creatinine plus ver.2.

The following table compares the CREATININE (Enzymatic) with the predicate device.
Table 1

Intended Use	For *in vitro* diagnostic use in the quantitative determination of creatinine concentration in human serum, plasma or urine on T60 instrument using enzymatic method.	The cassette COBAS INTEGRA Creatinine plus ver.2 (CREAP) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative determination of the creatinine concentration in serum, plasma and urine.
Indication for Use	The CREATININE (Enzymatic) is intended for quantitative *in-vitro* diagnostic determination of creatinine concentration in human serum, plasma (Li-heparin) or urine using T60 Clinical Chemistry Analyzers. Measurement of creatinine levels aids in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.	See intended use.
Assay Protocol	Enzymatic colorimetric assay	Enzymatic colorimetric assay
Traceability/Standardization	The value of Creatinine has been assigned by using NIST SRM 967 (for serum) and NIST SRM 914a (for urine)	Method has been standardized against ID/MS
Sample Type	Serum, plasma (Li-heparin) and urine	Serum, plasma (Li-heparin, K3-EDTA) and urine
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiry date printed on the label.	Shelf life at 2 to 8 °C until the expiration date on cassette.

Expected Values	Serum/plasma Male: 0.67 – 1.17 mg/dL Female: 0.51 – 0.95 mg/dL Urine Male: 40 – 278 mg/dL Female: 29 – 226 mg/dL	Serum, plasma: Adults Females: 0.51 – 0.95 mg/dL Males: 0.67 – 1.17 mg/dL Children Neonates (premature): 0.33 – 0.98 mg/dL Neonates (full term): 0.31 – 0.88 mg/dL 2 - 12 m: 0.16 – 0.39 mg/dL 1 -<3 y: 0.18 – 0.35 mg/dL 3 -<5 y: 0.26 – 0.42 mg/dL 5 -<7 y: 0.29 – 0.47 mg/dL 7 -<9 y: 0.34 – 0.53 mg/dL 9 -<11 y: 0.33 – 0.64 mg/dL 11-<13y: 0.44 – 0.68 mg/dL 13-<15y: 0.46 – 0.77 mg/dL Urine: First morning urine: Females: 29 – 226 mg/dL Males: 40 – 278 mg/dL 24-hour urine: Females: 720 – 1510 mg/24h Males: 980 – 2200 mg/24h Creatinine clearance: 66 - 143 mL/min
Instrument	T60 and DPC T60i, DPC T60i Kusti	Cobas Integra 700
Measuring Range	Serum, plasma: 0.11 – 28 mg/dL Urine: 2.3 – 452 mg/dL	Serum, plasma: 0 – 30.5 mg/dL Urine: 0 – 452 mg/dL

Precision	**Serum/plasma:** **Within run** Level 0.43 mg/dL SD= 0.006 CV(%)= 1.5 Level 1.75 mg/dL SD=0.008 CV(%)= 0.4 Level 5.47 mg/dL SD= 0.021 CV(%)= 0.4 **Between run** Level 0.43 mg/dL SD= 0.002 CV(%)= 0.4 Level 1.75 mg/dL SD=0.008 CV(%)= 0.5 Level 5.47 mg/dL SD= 0.015 CV(%)= 0.3 **Total** Level 0.43 mg/dL SD= 0.009 CV(%)= 2.2 Level 1.75 mg/dL SD= 0.026 CV(%)= 1.5 Level 5.47 mg/dL SD= 0.076 CV(%)= 1.4 **Urine:** **Within run** Level 76 mg/dL SD= 0.7 CV(%)= 1.0 Level 90 mg/dL SD= 0.8 CV(%)= 0.8 Level 165 mg/dL SD= 1.4 CV(%)= 0.9 Level 251 mg/dL SD= 2.2 CV(%)= 0.9 **Between run** Level 76 mg/dL SD= 0.6 CV(%)= 0.8 Level 90 mg/dL SD= 0.4 CV(%)= 0.5 Level 165 mg/dL SD= 1.9 CV(%)= 1.2 Level 251 mg/dL SD= 2.3 CV(%)= 0.9	**Serum/plasma:** **Within run** Level 1.0 mg/dL CV(%)= 1.6 Level 3.7 mg/dL CV(%)= 0.7 **Between run** Level 1.0 mg/dL CV(%)= 1.3 Level 3.8 mg/dL CV(%)= 0.9 **Urine:** **Within run** Level 106 mg/dL CV(%)= 0.8 Level 231 mg/dL CV(%)= 1.8 **Between run** Level 108 mg/dL CV(%)= 2.0 Level 238 mg/dL CV(%)= 3.9

	Total Level 76 mg/dL SD= 2.7 CV(%)= 3.5 Level 90 mg/dL SD= 2.8 CV(%)= 3.1 Level 165 mg/dL SD= 5.7 CV(%)= 3.5 Level 251 mg/dL SD= 8.7 CV(%)= 3.5	
Method Comparison	**Serum:** y = 1.01x – 0.001 R = 1.000 Range 0.12 to 24 mg/dL N = 41 **Plasma :** Deming: y = 0.97 – 0.02 r = 1.000 Range 0.27 to 27.58 mg/dL N = 52 **Urine** : y = 1.03x + 1.34 R = 0.999 Range 2.33 to 422 mg/dL N = 135	Roche/Hitachi 917 analyzer **Serum**: y = 1.01x + 1.13 µmol/l r = 0.999 n = 53 range: 0.60 to 26.1 mg/dL **Urine:** y=0.94x + 0.63 mmol/l r = 0.998 n = 54 range: 14.7 to 406 mg/dL

Limitations	**Serum/plasma:** **Lipemia**: No interference found up to 1000 mg/dL (10 g/l) of Intralipid. **Hemolysate:** No interference found up to 1000 mg/dL (10 g/l) of hemoglobin. **Bilirubin, conjugated:** No interference found up to 17 mg/dL (300 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 23 mg/dL (400 µmol/l) of unconjugated bilirubin. **Ascorbic acid:** No interference found up to 1.70 mmol/L (30 mg/dL) of ascorbic acid **Creatine:** No interference found up to 1.53 mmol/L (20 mg/dL) of creatine **Drugs:** Levodopa and calcium dobesilate cause artificially low creatinine levels. **Urine:** **Hemolysate:** No interference found up to 1000 mg/dL (10 g/l) of hemoglobin. **Bilirubin, conjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of conjugated bilirubin. **Glucose:** No interference found up to 2500 mg/dL (139 mmol/l). **Ascorbic acid:** No interference found up to 100 mg/dL (5.7 mmol/l). **Drugs:** Levodopa causes artificially low results.	**Serum/plasma:** **Lipemia**: No significant interference up to a triglycerides level of 1000 mg/dL and Intralipid level of 1000 mg/dL. **Hemolysate:** No significant interference up to a hemoglobin level of 0.50 mmol/L (8 g/l) of hemoglobin. **Bilirubin:** No significant interference up to a bilirubin level of 340 µmol/l (20 mg/dL) **Ascorbic acid:** No significant interference up to an ascorbic acid level of 1.70 mmol/L (30 mg/dL) **Drugs:** Levodopa and calcium dobesilate cause artificially low creatinine levels at the tested drug level. DL-proline at a concentration of > 1mmol/L causes falsely high results. **Other:** No significant interference up to a creatine level of 1.53 mmol/L (20 mg/dL) **Urine:** **Drugs:** Levodopa causes artificially low results **Other:** No significant interference up to a creatine level of 3.05 mmol/L (40 mg/dL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 3 2007

Thermo Fisher Scientific
c/o Mr. Päivi Sormunen
Vice President of Industrial
Solutions and QRC
Ratastie 2, P.O. Box 100
01621 Vantaa, Finland

Re: k070824
Trade Name: Creatinine (enzymatic): sCal; Nortrol; Abtrol
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine test system.
Regulatory Class: Class II
Product Code: JFY, JIX, JJY
Dated: October 23, 2007
Received: October 25, 2007

Dear Mr. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K070824

Device Name: **CREATININE (Enzymatic)**
sCal
Nortrol
Abtrol

Indication For Use:

Creatinine (Enzymatic)

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070824